Biological Safety (Biosafety)

Los Alamos National Laboratory
Laboratory Implementation Requirements LIR 402-530-00.2
Issue Date: 11/25/98 (Revised 01/07/03) **Mandatory Document**

1.0 Introduction

Lessons Learned **Note: *Click here* for Lessons Learned that may apply to the requirements contained in this LIR**

1.1 Overview

This LIR specifies Los Alamos National Laboratory (LANL or the Laboratory) Biosafety Program requirements that shall be implemented for research, maintenance, and other operations that have the potential for contact with bioagents/biohazards. Engineering controls, standard practices and techniques, and facility design are required to protect the health of workers, the public, and the environment. LANL's Institutional Biosafety Committee (IBC), which includes both subject matter experts (SMEs) and independent peers, is the key to biosafety at LANL. No operations involving bioagents/biohazards, including collaborations and work for others (i.e., non-DOE work) shall be conducted at LANL without IBC review (see Attachment A). Operations involving bioagents/biohazards shall be conducted only by qualified, trained personnel after institutional acceptance of the work and concurrence by IBC, as required. For operations involving bioagents/biohazards performed for the National Institutes of Health (NIH), the Laboratory must follow specific NIH guidelines (see Sections 7.3.1.1 and 7.3.2.10 of this LIR). LANL has chosen to include these universally accepted guidelines in the Biosafety Standards for the Laboratory.

> **Note:** Attachment C contains useful biosafety internet sites. Attachment D is a summary of biosafety levels for infectious agents in accordance with NIH/CDC guidelines. Attachment E contains biosafety levels for activities in which infected vertebrate animals are used.

This document addresses four major areas: (1) laboratories or facilities (2) experimental or clinical laboratories; (3) activities involving infected vertebrate animals; and (4) incidental/accidental contact with infected wildlife. An operation may involve more than one of these areas, such as (1) and (2), e.g., using human blood as research media. Requirements for all the applicable areas must be considered for research proposals, activities, studies, and operations.

This LIR complements LPR 402-00-00, Appendix I, "Worker Health and Safety." Unless otherwise stated in the text, the requirements contained in this LIR are effective upon the issue date. See Attachment F for Recommended Major Implementation Criteria for Self-Assessment.

1.2 In This Document

2.0 Purpose

The purpose of this LIR shall be to establish requirements for protecting LANL employees, subcontractors, visiting researchers and the environment against disease resulting from exposure to bioagents/biohazards. These bioagents/biohazards shall include organisms that are potentially pathogenic in humans, i.e., infectious microorganisms and pathogens, *such* as bacteria, viruses, and fungi.

3.0 Scope and Applicability

This LIR shall apply to

- research activities conducted by LANL employees, subcontractors, and visiting researchers in laboratories or facilities in which bioagents/biohazards are manipulated, handled, or maintained;
- experimental or clinical laboratories whose personnel use or have potential contact with human blood or other fluids**,** primary tissues, or primary cells including health care settings and onsite first aid/cardiopulmonary resuscitation (CPR) response provided as part of official duties (see Attachment B);
- activities in which experimentally or naturally infected animals are used or handled (wildlife trapping and pest and rodent control); and
- other activities in which incidental/accidental contact with infected wildlife or insect vectors of disease may occur, e.g., during outdoor activities, field research, or in offices infested with mice.

4.0 Definitions

4.1 Acronyms

BSL	Biosafety level
BBP	Bloodborne pathogen
BSC	Biological safety cabinets
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
DNA	Deoxyribonucleic acid
DOT	Department of Transportation
ECP	Exposure control plan
FC	Facility coordinator
FMU	Facility management unit
HBV	Hepatitis B virus
HCP	Hazard Control Plan
HEPA	High-efficiency particulate air (filter)
HIV	Human immunodeficiency virus
IACUC	Institutional Animal Care and Use Committee
IBC	Institutional Biosafety Committee
LIR	Laboratory implementation requirement
NIH	National Institutes of Health
PI	Principal investigator
PPE	Personal protective equipment
SOP	Standard operating procedure
SME	Subject matter expert
SSS	Support services subcontractor
UCOP	University of California Office of the President

4.2 Definitions

Bioagent/biohazard—An organism or product of an organism that presents a risk to humans i.e., infectious microorganisms, biological allergens, and toxins, such as *c. botulinum* and *legionella pneumophila*).

Bioagent/biohazard toxin—Any substance produced from a microorganism (e.g., bacterium, virus, fungus, or protozoan), that has the potential to cause injury or illness in humans.

Biosafety—A graded approach based on the Centers for Disease Control (CDC) publication, "Biosafety in Microbiological and Biomedical Laboratories," which describes laboratory practices and techniques, safety equipment, and laboratory facilities.

Biosafety Level 1 (BSL-1)—A level that includes bioagents that are not known to cause disease in healthy adults.

Biosafety Level 2 (BSL-2)—A level that includes bioagents associated with human disease and hazards from autoinoculation, ingestion, and mucous membrane exposures.

Biosafety Level 3 (BSL-3)—A level that includes indigenous or exotic bioagents communicated via aerosols ~~and~~ that produce diseases with serious or lethal consequences.

Biosafety Level 4 (BSL-4)—A level that includes extremely dangerous or exotic bioagents that pose high risk of life-threatening disease, aerosol-transmitted laboratory infections, and related agents for which the risk of transmission is unknown.

Blood—Human blood, components of human blood, and products made from human blood.

Bloodborne pathogens—Pathogenic microorganisms that are present in human blood and that cause disease in humans. These pathogens include, but are not limited to, HBV and HIV.

Contaminated—Refers to the presence or the reasonably anticipated presence of human blood or potentially infectious materials on an item or surface.

Contaminated laundry—Laundry that has been soiled with human blood or other infectious materials or that may contain sharps.

Contaminated sharps—Any contaminated object that can penetrate the skin, including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires.

Decontamination—The use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where it is no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

Disinfectant solution—A hypochlorite solution prepared by mixing 3 tablespoons of household bleach in 1 gallon of water; a commercial disinfectant.

Engineering controls—Controls that isolate or remove bioagents/biohazards and bloodborne pathogen hazards from the workplace.

Etiologic agent—An organism that causes disease.

Exposure incident—A specific eye, mouth, other mucous membrane, nonintact skin, or parenteral contact with human blood or other potentially infectious materials that results from performance of an employee's duties.

Hand-washing facilities—A facility that provides an adequate supply of running potable water, soap, and single-use towels or hot-air drying machines.

Hantavirus Pulmonary Syndrome—a zoonotic respiratory disease caused by a hantavirus. Hantavirus is carried in the urine, saliva, and feces of rodents, in particular, rats and mice.

Heavily infested—Extreme infestation conditions. Piles of droppings indicating nesting sites, rodent nests visible in the interior of the building, or numerous dead animals are present. The presence of droppings alone indicates infestation, but not necessarily a heavy infestation.

High-risk areas—Rural and wilderness areas and urban areas close to fields or chaparral where the risk of exposure to hantavirus is high.

Infested—Evidence of rodents is present inside a building. Rodents have been seen, droppings are present, or food has been nibbled by rodents.

Licensed health care professional—A person whose legally permitted scope of practice allows him or her to independently perform HBV vaccinations and postexposure evaluation and follow-up.

Low-risk area—Urban area where the risk of hantavirus exposure is low.

Occupational exposure—Reasonably anticipated skin, eye, mucous membrane, or parenteral contact with human blood or other potentially infectious materials that may result from the performance of an employee's duties.

Other potentially infectious materials—Refers to the following human body fluids: (1) semen, vaginal secretion, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; (2) any unfixed tissue or organ (other than intact skin) from a human (living or dead); and (3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solution; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

Parenteral—Refers to piercing mucous membranes or the skin barrier through such events as needle sticks, human bites, cuts, and abrasions.

Personal protective equipment—Specialized clothing worn by an employee for protection.

Primary barriers—A term used to describe safety equipment, such as biological safety cabinets (Classes I, II, and III), enclosed containers, and other engineering controls designed to remove or minimize exposures to bioagents/biohazards.

Qualified personnel—Personnel who have received training in the transmission of disease by bioagents/biohazards, including bloodborne pathogens, and who are assigned to conduct tasks involving potential exposure to bioagents/biohazards, including bloodborne pathogens or other potentially infectious materials.

Regulated waste—Liquid or semiliquid human blood or other potentially infectious material; contaminated items that release human blood or other potentially infectious materials in a liquid

or semiliquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing human blood or other potentially infectious materials. Guidance Note: These wastes, as well as contaminated animal carcasses and bedding are regulated in the State of New Mexico as "infectious wastes," which is a subcategory of New Mexico Special Waste. See LIR 404-00-04 for storage and handling requirements.

Secondary barriers—A term used to describe features of the overall design of a facility that are intended to prevent exposure to bioagents/biohazards. The interior layout of a laboratory, level of controlled access, safety equipment provided, and the type of ventilation system installed are secondary barriers that determine the facility's biosafety level and what bioagents/biohazards can be authorized for the facility.

Source individual—Any living or dead individual whose blood or other potentially infectious body fluids may be a source of exposure to employees, including trauma victims.

Sterilize—Use of a physical or chemical procedure to destroy all microbial life, including highly resistant bacterial endospores.

Universal precautions—An approach to infection control in which all human blood and certain human fluids are treated as if known to carry HIV, HBV, and other bloodborne pathogens.

Work practice controls—Controls that reduce the likelihood of exposure by altering the manner in which a task is performed.

Zoonosis—Diseases such as rabies, hantavirus, or plague that can be transmitted from animals to humans.

5.0 Precautions and Limitations

Not applicable.

6.0 Implementation Requirements

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6.1 Institutional Biosafety Committee

This panel of safety matter experts and independent peers in biosafety and public health shall provide assurance to Laboratory management, employees, and members of the public that due care is being exercised for operations involving bioagents/biohazards. The existence and composition of the IBC shall be governed by National Institutes of Health guidelines and shall include researchers from divisions that perform work involving biological operations, occupational medicine and industrial hygiene personnel, community health care providers, and at least two members of the community not associated with the institution or the work. This committee shall report to the Associate Director for Operations.

The IBC shall:

1. have the sole authority to review and approve all proposals, activities, and studies involving bioagents/biohazards associated with BSL-2 and above, including but not limited to work with potential pathogens, work with DNA from pathogenic organisms, work with or potential exposure to bloodborne pathogens, and bioagents/biohazards associated with animal and plant work. This review shall be in accordance with biosafety standards contained in this document (Section 7.3.1) and shall be based on: the biosafety level of the work; the perceived risk; the experience of the investigators; the training of the workers; and the use of required facilities, equipment and operational procedures;
2. serve as the advisory body to the Laboratory Director, the Associate Director for Operations and Division Leaders for operations involving bioagents/biohazards;
3. identify special-emphasis areas for the Biosafety Program;
4. foster communication on biosafety issues throughout the Laboratory;
5. promote continuous improvement of the Biosafety Program;
6. evaluate adoption of new or revised standards and requirements for biosafety work;
7. function as a resource for the Laboratory, providing guidance and technical support on biosafety issues;
8. provide an annual review and summary of documentation for approved proposals, activities, and studies; and
9. operate in accordance with the formal IBC procedures as set out in the IBC Operational Support Tool (OST 402-530-00.0 click here).

6.2 Safety-Responsible Line Managers

6.2.1 Laboratories and Facilities in Which Bioagents/Biohazards Are Manipulated, Handled, or Maintained

Safety-responsible line managers shall

- institute biosafety measures in accordance with Sections 7.3.1.1 and 7.3.2.10 of this LIR;
- obtain from the Laboratory's IBC an initial review, and an annual review thereafter, of all research proposals, activities, and studies (including but not limited to work for others) involving bioagents/biohazards of BSL-2, BSL-3, and BSL-4, using the forms in Attachment A);
- ensure that IBC comments and recommendations are addressed before work commences;
- submit any changes in research proposals, activities, and studies to the Laboratory's IBC and ensure that IBC comments and recommendations are addressed before the changes are implemented;
- ensure that HCPs are created, for all operations involving bioagents/biohazards, including BSL-1, BSL-2, BSL-3, and BSL-4;
- evaluate academic and work experience of personnel working with bioagents/biohazards to ensure that they are qualified;
- maintain the facilities (secondary barriers) for which they are responsible to ensure protection of workers from bioagents/biohazards;

- control access to laboratories and field research areas;
- ensure independent assessment of operations involving bioagents/biohazards;
- implement the LANL exposure control plan (see Attachment B), annotating for additional job classifications or tasks, when the potential for exposure to bloodborne pathogens or other potentially infectious material exists; and
- ensure that procured items are purchased from qualified suppliers and that items are inspected or certified upon receipt.

6.2.2 Activities in Which Experimentally or Naturally Infected Animals Are Used or Handled

Safety-responsible line managers shall

- institute requirements of Section 6.2.1;
- ensure that universal precautions are followed when handling animal blood,
- ensure that all animal work is reviewed by LANL's IACUC, and
- ensure that procured items are purchased from qualified suppliers and items are inspected or certified upon receipt.

6.2.3 Health Care Settings, Clinical Laboratories and Other Operations in Which There Is Potential for Exposure to Blood or Other Potentially Infectious Materials

Safety-responsible line managers shall

- institute biosafety measures in accordance with Section 7.3.2.7 and Attachment B;
- implement the LANL exposure control plan (see Attachment B), annotating for additional job classifications or tasks, when the potential for exposure to bloodborne pathogens or other potentially infectious material exists; and
- ensure that procured items are purchased from qualified suppliers and items are inspected or certified upon receipt.

6.2.4 First-Aid and CPR

Safety-responsible line managers shall ensure that first-aid and CPR responders performing onsite first aid/CPR as part of official duties:

- follow the procedures in Section 6.6.4
- institute biosafety measures (i.e., universal precautions) in accordance with Section 7.3.2.7 and Attachment B;
- follow the LANL Exposure Control Plan (see Attachment B) when potential exposure to bloodborne pathogens or other potentially infectious material may exist; and
- ensure that procured items are purchased from qualified suppliers and that items are inspected or certified upon receipt.

6.2.5 Incidental/Accidental Contact with Infected Wildlife

Safety-responsible line managers shall ensure that employees

- follow the procedures in Section 6.6.5 and
- ensure that procured items are purchased from qualified suppliers and that items are inspected or certified upon receipt.

6.3 ESH-5

ESH-5 shall

- determine the effectiveness of the Biosafety Program through assessments and evaluations;
- assist in implementing the Biosafety Program;
- evaluate the impact of biosafety requirements on the Laboratory;,
- ensure the dissemination of biosafety information, such as accident reports and lessons learned;
- appoint the institutional biosafety officer, who serves on and supports the IBC;
- ensure that the institutional biosafety officer reviews protocols and procedures involving biotoxins;
- assist facility managers and LANL's Support Services Subcontractor (SSS) with issues associated with pest and rodent control; and
- provide guidance and training materials to workers who have incidental/accidental contact with infected wildlife.

6.4 ESH-2

ESH-2 shall

- provide a graded approach to medical surveillance for all activities involving bioagents/biohazards and potential exposures to bloodborne pathogens;
- provide biohazard needle containers for Laboratory employees with diabetes, at their request;
- serve on and support the IBC;
- provide immunizations;
- provide medical evaluation and treatment of work-related injuries and infectious diseases and injuries;
- provide animal handlers with education on zoonoses of interest and appropriate immunization, serologic studies and medical surveillance; and
- provide a graded approach to medical surveillance for all activities involving wildlife trapping and pest control.

6.5 BUS-4

In accordance with LIR 405-10-01, "Packaging and Transportation," BUS-4 shall provide requirements pertaining to transportation of bioagents/biohazards.

6.6 Workers

6.6.1 Laboratories and Facilities In Which Bioagents/Biohazards Are Manipulated, Handled, or Maintained

Workers who work in these laboratories and facilities shall

- follow the requirements of applicable research protocol, HCPs, SOPs, and this LIR;
- institute biosafety measures in accordance with Section 7.3.1.1 or 7.3.2.10 of this LIR;
- control access to laboratories and field research areas; follow the applicable exposure control plan (see Attachment B) when the potential for exposure to bloodborne pathogens and other potentially infectious material exists; and.
- ensure that procured items are purchased from qualified suppliers and that items are inspected or certified upon receipt.

6.6.2 Activities in Which Experimentally or Naturally Infected Animals Are Used or Handled

Workers shall

- follow the requirements of applicable research protocol, HCPs, SOPs, and this LIR;
- institute biosafety measures in accordance with Section 7.3.1.1, or 7.3.2.10 of this LIR;
- control access to laboratories and field research areas;
- follow the applicable exposure control plan (see Attachment B) when the potential for exposure to bloodborne pathogens or other potentially infectious material exists; and
- ensure that exposure to zoonoses, e.g., tetanus, rabies, plague, Lyme disease, Rocky Mountain spotted fever, and hantavirus, are minimized, by implementing the following work practices:
    - perform first aid immediately and contact ESH-2 immediately if an animal bites, scratches, or causes other injury.
    - wear insect repellent and check for ticks regularly when performing field research or fieldwork.
    - use a trap that kills or humanely captures the animal. If trapping a rodent for the purpose of controlling rodent exposure in an occupied work area, a trap that kills the rodent shall be used. Contact facility personnel to dispose of trapped animals.
    - when disposing of trapped animals, wear, at a minimum, double rubber gloves for handling any wildlife material or surface that wildlife may have contacted. Additional protection may be warranted for live trapping.
    - do not use vacuums for cleaning up rodent droppings. Fecal material shall be saturated with an EPA-approved disinfectant, e.g., 10% bleach, and collected in a plastic bag.
    - launder contaminated clothing with detergent and hot water.
    - soak contaminated materials with an appropriate disinfectant and double-bag them in plastic for proper waste disposal.

  Guidance Note: ESH-5 has a copy of a booklet called Safety Guidelines for Field Research, which provides useful general information on fieldwork hazards and precautions.

- ensure that procured items are purchased from qualified suppliers and items are inspected or certified upon receipt.

- **Health Care Settings, Clinical Laboratories and Other Operations in Which There Is Potential for Exposure to Blood or Other Potentially Infectious Materials**

Workers shall

- follow the requirements of applicable HCPs, ECPs, SOPs, and this LIR;
- institute biosafety measures in accordance with Section 7.3.2.7 and Attachment B;
- follow the applicable exposure control plan (see Attachment B); and
- ensure that procured items are purchased from qualified suppliers and items are inspected or certified upon receipt.

6.6.4 First-Aid and CPR

Workers shall

- follow the requirements of applicable HCPs, SOPs, and this LIR (Attachment B);
- institute biosafety measures (i.e., universal precautions) in accordance with Section 7.3.2.7 and Attachment B;
- follow the LANL Exposure Control Plan (see Attachment B) when the potential for exposure to bloodborne pathogens or to other potentially infectious material exists during provision of first aid or CPR on-site; and
- ensure that procured items are purchased from qualified suppliers and that items are inspected or certified upon receipt.

6.6.5 Incidental/Accidental Contact with Infected Wildlife

Workers shall

- follow the requirements of applicable HCPs and this LIR,
- ensure that procured items are purchased from qualified suppliers and items are inspected or certified upon receipt,
- reduce the potential for incidental and accidental exposure to rodents or other wild animals and their waste by observing appropriate work practices,

  Guidance Note: Suggested work practices for reducing the potential for incidental and accidental exposure include:
  - reducing the amount of food and water available to rodents;
  - keeping food covered or in a refrigerator;
  - cleaning dirty dishes promptly;
  - keeping all bulk grains and animal foods outside in secure containers;
  - improving housekeeping in work spaces and storage areas to limit the availability of nesting areas;
  - placing garbage in rodent-proof containers and empty the containers regularly (preferably daily)
  - sealing, covering, or screening all openings that are large enough for mice to enter (anything over 1/4 inch), which includes areas where pipes and wires enter the building; and

- contact the FC if animal nests, droppings, or carcasses are discovered in a work area. If the work area does not have a designated FC, the SSS must be contacted to properly disinfect and remove these items. The SSS shall disinfect the area and dispose of the contaminated materials in accordance with SSS procedures.

7.0 References

7.1 Document Ownership

The OIC for this document shall be ESH-5.

7.2 Referrals

Referrals are listed in Attachment E.

7.3 Documents

7.3.1 Biosafety Standards

7.3.1.1 "Biosafety in Microbiological and Biomedical Laboratories", U.S. Department of Health and Human Services, Public Health Service, Centers for Disease control and Prevention and National Institutes of Health, 4th Edition, May 1999. (BMBL)

7.3.1.2 Title 42 CFR Part 72 – Interstate Shipment of Etiologic Agents

7.3.1.3 42 CFR Part 73/42 CFR Part 1003 "Possession, Use, and Transfer of Select Agents and Toxins" and

7.3.1.4 7 CFR Part 331/9 CFR Part 121 "Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer of Biological Agents and Toxins".

7.3.2 Other References

7.3.2.1 US Department of Health and Human Services. "Foreign Quarantine Regulations," Public Health Service, Title 42, Code of Federal Regulations, Part 71.156, Washington, DC.

7.3.2.2 Los Alamos National Laboratory document LA-UR-98-2837, "Integrated Safety Management."

7.3.2.3 Los Alamos National Laboratory document LIR 404-00-04, "Managing Solid Waste."

7.3.2.4 Los Alamos National Laboratory document LIR 405-10-01, "Packaging and Transportation."

7.3.2.5 Los Alamos National Laboratory document LPR 402-00-00, "Worker Health and Safety."

7.3.2.6 Los Alamos National Laboratory document LIR 307-01-01, "Safety Self-Assessments."

7.3.2.7 OSHA (Occupational Safety and Health Administration) 1991. "Occupational Exposure to Bloodborne Pathogens," Final Rule, Federal Register 56:64175-64182.

7.3.2.8 World Health Organization, June 1983. "Laboratory Biosafety Manual," ISBN: 9241541679.

7.3.2.9 World Health Organization, "Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens," WHO/EMC/97.3, Geneva, Switzerland.

7.3.2.10 US Department of Health and Human Services May 1998. "Guidelines for Research Involving Recombinant DNA Molecules," effective June 24, 1994, Federal Register (59 FR 34496), July 5, 1994.

7.3.3 Required Records

The following records shall be maintained.

- ESH-2: medical records and vaccination declination forms.
- ESH-5: inspections or evaluations performed by the Biological Safety Officer and evaluations performed by other members of ESH-5.
- IBC: projects reviewed and records of decisions.

8.0 Attachments

Attachment Institutional Biosafety Committee Forms
Attachment B LANL Bloodborne Pathogen Exposure Control Plan
Attachment C Useful Biosafety Internet Sites
Attachment D Summary of Biosafety Levels for Infectious Agents for Laboratories or Facilities where Bioagents/Biohazards are Manipulated, Handled, or Maintained
Attachment E Summary of Biosafety Levels for Activities in Which Experimentally or Naturally Infected Vertebrate Animals Are Used or Handled

Attachment F Recommended Major Implementation Criteria for Self-Assessment

ATTACHMENT A

INSTITUTIONAL BIOSAFETY COMMITTEE FORMS

IBC Application **Investigator _____**

PROPOSAL FOR EXPERIMENTS INVOLVING BIOHAZARDOUS AGENTS
INSTITUTIONAL BIOSAFETY COMMITTEE

Date Submitted_____(to MS K494) Date required _____

Investigator _____Signature _____

Group Leader _____Signature _____

Bioagent _____ Recombinant DNA? ___ Y ___ N

NIH activity? ___ Y ___ N

CDC/NIH Biosafety Level _____

Proposed experiment, study, or activity:

Provide a brief rationale and an experimental protocol. Explain why the use of a potentially biohazardous agent is necessary, how the agent will be used, and the quantities that will be handled. If this work involves recombinant DNA, specify the vector(s) and cell system(s) to be used.

Is there a hazard control plan (HCP) on file for this work? If not, you must prepare an HCP. (If completed, please include a copy of the HCP with the application and reference appropriate questions in the form below.)

IBC Application **Investigator _____**

Experimental Logistics

Detail the source of the bioagent, provide a list of all laboratory buildings and rooms in which the bioagents will be handled or stored, and explain maintenance procedures for future use of the bioagent, if applicable.

Personnel

List the names and affiliations of all personnel who will be involved in experiments with the bioagent, including persons outside LANL. Personnel listed here must be aware of any potential risks and must have received the proper training for handling the bioagent.

Time Schedule

Explain the time schedule and duration of use of the bioagent.

Experimental Animals

Describe in detail the use of experimental animals, including species, number used, source of animals, housing facilities, and potential infection of animals with bioagent. Explain any special conditions and protocols required by the Laboratory's Animal Care and Use Committee.

IBC Application **Investigator _____**

Special Procedures

In each of the following categories, describe in detail the procedures and equipment used to prevent accidental release of, or exposure to, the bioagent.

Containment Equipment

Protective Clothing

Ventilation

Waste Disposal/Disinfection

Monitoring

Describe in detail the methods to be used to validate the adequacy of the experimental protocol and safety procedures in preventing accidental release of the bioagent and/or exposure of personnel.

IBC Application **Investigator _____**

Emergency Information

In each of the following areas, describe in detail any special instructions or procedures to be followed in the event of an accident (fire, explosion, bioagent release). Explain how and where these instructions will be posted for easy use during an emergency.

Fire and Emergency Crews

Power Failure

Emergency Contacts

Assessment of Potential Hazard

Based on the above information and your own experience with biohazardous agents, provide an assessment of the relative hazard of conducting this project. Include the risks of exposure and infection for laboratory personnel, experimental animals, and the surrounding community. Describe in detail the consequences of infecting humans with this bioagent. Provide a bibliography of research that would assist the committee in evaluating your assessment and any other material you feel would be helpful in evaluating this proposal.

ATTACHMENT B

LANL BLOODBORNE PATHOGEN EXPOSURE CONTROL PLAN

B.1.0 Laboratory Exposure Control Plan

This plan shall serve as the LANL Bloodborne Pathogen Exposure Control Plan (ECP). The Laboratory's Bloodborne Pathogen Program shall consist of (1) identifying job classifications and tasks that involve potential occupational exposure to bloodborne pathogens and other potentially infectious materials and (2) ensuring that an adequate ECP has been implemented. The primary elements of the ECP shall be

- exposure determination;
- control methods [including the use of universal precautions, engineering and work practice controls, personal protective equipment (PPE), and proper housekeeping and labeling],
- Hepatitis B vaccination and postexposure follow-up;
- employee information and training; and
- record keeping.

Guidance Note: This plan can be supplemented by organizational specific ECPs, (e.g., ESH-2's ECP), and/or HCPs. It can also be used as is, annotated as necessary for additional job classification or tasks for other Laboratory organizations. To help organizations ensure compliance with LIR 300-00-01, "Safe Work Practices,' and the OSHA Bloodborne Pathogen Standard, a comparison of HCP and ECP requirements is shown in Table B-1.

B.1.1 Exposure Determination

The job classifications and tasks that involve potential occupational exposure are listed below:

- Medical Personnel—Tasks in this job classification include administration of medical care.
- Investigation and Remediation Personnel at Infectious Waste Sites—Tasks in this job classification include air, soil and water sampling, waste-handling and removal operations, and other duties at sites where direct contact with infectious waste, e.g., medical waste, occurs.
- Other Job Classifications—Tasks in this job classification include all tasks in which anticipated or actual exposure to human or animal blood or other potentially infectious materials could occur. If applicable, a specific exposure determination by job classification and task shall be completed.
- SSS janitorial personnel who may come in contact with human or animal blood or other potentially infectious materials.
- First-Aid-and CPR-Qualified Individuals—Tasks in this job classification include onsite administration of first aid and/or CPR performed as part of official duties.

First aid and CPR-qualified individuals shall be briefed on the contents of this LIR only as it relates to first aid and CPR. ESH-2 shall offer to these individuals only postexposure Hepatitis B evaluation and follow-up. Pre-exposure vaccination shall not be required for individuals who do not have routine occupational exposure to bloodborne pathogens. Any employee who is exposed to blood or other potentially infectious materials when rendering first aid or providing CPR must seek medical attention within 24 hours after exposure to receive effective post-exposure Hepatitis B immunization.

B.1.2 Universal Precautions

Universal precautions, which treat human or animal blood and certain human or animal bodily fluids, as if they were known to be infectious, shall be used to prevent direct physical contact. These precautions shall include the use of barriers, isolation, PPE, and first-aid supplies containing a face shield for use in mouth-to-mouth resuscitation (artificial respiration) when necessary.

B.1.3 Engineering and Work Practice Controls

The following engineering and work practice controls shall be implemented:

- Drawing blood or collecting urine samples for private reasons, e.g., life insurance policies, is prohibited on Laboratory property.

- Engineering and work practice controls to eliminate or minimize employee exposure. PPE shall be used only when engineering and work practice controls do not adequately control occupational exposure.

- Engineering controls used examined, maintained, and replaced on a regular schedule to ensure their effectiveness.

Guidance Note: Examples of an engineering control include the use of a sharps disposal container or use of a container specially marked for contaminated first-aid materials.

- Work practice controls that are implemented at work sites where the potential for occupational exposure exists.

  - Hand-washing facilities provided on each site. If provision of facilities is not feasible, antiseptic hand cleansers or towelettes are used immediately, followed by soap and running water as soon as possible.

  - Employees wash hands immediately or as soon as possible after removing gloves or coming in contact with human or animal blood or other potentially infectious materials.

  - Employees are not to eat, drink, smoke, apply cosmetics, or handle contact lenses in areas of potential exposure.

- Equipment that may have been contaminated with human or animal blood or other infectious materials shall be examined and decontaminated, if feasible. If equipment cannot be decontaminated, it shall be labeled as a biohazard. Information regarding the biohazard shall be communicated to all handling, shipping, and service personnel.

B.1.4 Personal Protective Equipment

Employees shall observe the following PPE requirements:

- Use PPE that does not permit human or animal blood or other potentially infectious materials to reach employees' clothes or body under normal conditions and duration of use.
- PPE provided, maintained, and properly disposed at each work site where potential exposure exists. PPE shall be accessible at each work site and shall include hypoallergenic gloves or alternatives as necessary.
- Remove potentially contaminated PPE before exiting the work area and shall place it in a regulated container for disposal.

- Appropriate gloves (e.g., latex and/or puncture-resistant gloves) worn when exposure to animal, human, or other potentially infectious materials is expected and when contaminated items or surfaces are being handled.
- Disposable gloves are not to be reused. Replace if torn or punctured or their ability to function as a barrier has been compromised.
- Surgical masks, in combination with eye protection (e.g., goggles or glasses with side shields or face shield) worn when splashes may contaminate eyes, nose, or mouth.

Potential exposure to *m. Tuberculosis* shall be governed under the requirements of Section 6.1 of this LIR.

B.1.5 Housekeeping and Labeling

Employees shall practice the following good housekeeping and labeling practices**:**

- All equipment and environmental surfaces cleaned and decontaminated after contact with animal, human, or other potentially infectious materials.
- Regulated waste placed in containers that have lids that can be tightly closed, that are constructed to prevent leaks, and that are labeled with a biohazard label and sealed before moving.
- All contaminated laundry disposed of as regulated waste or sent to a laundry facility where personnel are experienced in handling infectious waste. Complete information regarding the nature of the waste and potential hazards shall be disclosed to the laundry facility.
- All regulated waste containers shall be labeled with the "Biohazard" legend.
- All infectious waste containers shall be labeled “New Mexico Special Waste

B.1.6 Hepatitis B Virus Vaccination and Postexposure Follow-Up

Qualified personnel in ESH-2 shall administer all HBV vaccinations, following the procedures recommended by the US Public Health Service and complying with the Occupational Safety and Health Administration (OSHA) standard for Occupational Exposure to Bloodborne Pathogens (29 CFR 1910.1030). Only postexposure vaccinations shall be required for first aid and CPR responders, as defined in Section 3.0.

B.1.7 Employee Information and Training

Training shall be provided annually to employees governed by the requirements of this LIR, which includes qualified first-aid personnel, site investigation and remediation personnel who work at infectious-waste sites, and other employees whose work may expose them to bloodborne pathogens. Information and training shall include the following:

- an accessible copy of OSHA regulation 29 CFR 1910.1030 and an explanation of its contents;
- a general explanation of the epidemiology and symptoms of bloodborne diseases;
- an explanation of the modes of transmission of bloodborne pathogens;
- an explanation of the ECP and the means by which an employee can obtain a copy of the written plan;
- an explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to animal, human, and other potentially infectious materials;
- an explanation of the use and limitations of methods that prevent or reduce exposure; including appropriate engineering controls, work practices, and personal protective equipment;
- information on the types, proper use, location, removal, handling, decontamination, and disposal of PPE,

- an explanation of the basis for selecting PPE;
- information on the HBV vaccine, including information on its efficacy, safety of administration, benefits of being vaccinated, and availability of free vaccinations;
- information on the appropriate actions to take and persons to contact in an incident involving animal, human, or other potentially infectious materials;
- an explanation of the procedure to follow if exposure occurs, including the method of reporting the incident and the medical follow-up available;
- information on the postexposure evaluation and follow-up that the employer must provide for the employee following an exposure incident;
- an explanation of the signs and labels and/or color coding required by 29 CFR 1910.1030 (g)(1); and
- an opportunity for posing questions to and receiving answers from the person conducting the training session.

Guidance Note: Training may also be provided as site-specific training.

B.2.0 Responsibilities

B.2.1 Safety-Responsible Line Managers

Safety-responsible managers of bloodborne pathogens (BBP) workers shall

- ensure that procured items are purchased from qualified suppliers and that items are inspected or certified upon receipt;
- conduct exposure determinations;
- develop an ECP;
- ensure that an ECP is accessible to employees;
- ensure that employees are aware of medical surveillance offerings and the associated ability to decline medical surveillance offerings;
- ensure that employees are enrolled in medical surveillance programs provided by ESH-2;
- use engineering and work practice controls;
- examine, maintain, and upgrade engineering controls, as needed;
- provide hand-washing facilities at appropriate locations;
- determine proper waste disposal procedures for potentially infected materials;
- provide required PPE and be responsible for assuring PIs of regular laundering, repair, and replacement of PPE;
- ensure independent assessment of their biological operations; and
- supply required placards and labels.

B2.2 ESH-5

ESH-5 shall

- develop an exposure control plan (ECP) template for use by Laboratory personnel,

Guidance Note: An ECP may be included as part of a Safe Work Practices Hazard Control Plan (HCP). Necessary additions to the HCP are shown in Table B-1 (located at the end of this attachment).

- assist the safety-responsible line manager in implementing the ECP, including the exposure determination for similarly exposed employee groups,
- assist ESH-2 in establishing procedures for evaluating exposure incidents,
- assist ESH-2 with evaluating exposure incidents, and
- provide oversight of biosafety activities approved by the IBC.

B.2.3 ESH-2

ESH-2 shall

- determine a schedule and method of implementation for Hepatitis B vaccination and postexposure evaluation and follow-up,
- determine procedures to evaluate exposure incidents,
- conduct exposure incident evaluations, and
- administer the Hepatitis B vaccination program.

TABLE B-1

COMPARISION OF REQUIREMENTS OF SAFE WORK PRACTICES HAZARD CONTROL PLAN* AND AN EXPOSURE CONTROL PLAN

Requirements for Safe Work Practices Hazard Control Plan	**Requirements for Bloodborne Pathogens Exposure Control Plan**
Combination of documents that contain the essential information or reference other documents.	Not applicable
Description of the work covered by the plan, including sufficient detail to enable the reader to understand the environment in which the hazards could occur and the reasons for establishing the controls.	Exposure Determination: tasks
Identification of all significant hazards based on a systematic evaluation.	Exposure Determination: job classifications and task
Estimate of the overall initial risk to determine the level of review required	Not applicable
Listing of Laboratory facilities, activities, and operational requirements and restrictions directly related to the work.	Exposure Determination: job classifications and task
Description of the controls that have been developed or modified to achieve acceptable risk and that constitute the hazard control system. Description of wastes and proper storage and disposal practices.	Universal precautions, engineering and work practice controls, PPE
Description of the knowledge, skills, and abilities necessary to use the controls and perform the work safely and the training, both formal and on-the-job, necessary to obtain the requisite knowledge and skills	Employee Information and Training
Description of wastes	Housekeeping and labeling
Estimate of residual risk with controls, considering failures of controls, equipment, utilities, facility systems, procedures, and human factors.	Not applicable
Emergency actions	Not applicable
Change control process and method for notifying affected personnel	Not applicable
Cover Sheet Review Title Identifying Work Next authorization review date Signature of authorizer If initial risk is medium, name of SME and independent peer who reviewed the document. If initial risk is high, signatures of SME and independent peer who concurred with the document	Not applicable

Authorization of Workers Work having residual risk: signature of supervisor Work having low or medium residual risk: Signature of appropriate line manager	Not applicable

*Requirements copied verbatim from LIR 300-00-02.0, “Documentation of Safe Work Practices.”

ATTACHMENT C
Guidance
USEFUL BIOSAFETY INTERNET SITES

http://www.cdc.gov/od/ohs/biosfty/bmbl/bmbl-1.htm

Contains the Centers for Disease Control/National Institutes of Health (CDC/NIH) publication, "Biosafety in Microbiological and Biomedical Research Laboratories."

http://www.nih.gov/od/orda/toc.htm

Contains the "Guidelines for Research Involving Recombinant DNA Molecules," also known as "the NIH guidelines."

http://www-ehs.ucsd.edu/biosafe.htm

Home page of the environmental health and safety (EHS) at the University of California—San Diego. Offers an excellent example of a biosafety manual called the "Orange Book."

http://www.osha-slc.gov/OshStd_data/1910_1030.html

Contains OSHA's Blood-Borne Pathogens Standard

http://www.wh.org/

Contains World Health Organization information.

http://www.who.int/emc/biosafety.html

Contains the World Health Organization's "Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens."

ATTACHMENT D
SUMMARY OF BIOSAFETY LEVELS FOR LABORATORIES OR FACILITIES WHERE BIOAGENTS/BIOHAZARDS ARE MANIPULATED, HANDLED, OR MAINTAINED[a, b]

Biosafety Level (BSL)	Agents	Practices	Safety Equipment (Primary Barrier)	Facilities (Secondary Barrier)
1	Not known to cause disease in healthy adults.	Standard microbiological practices.	None required.	Open bench top sink required.
2	Associated with human disease; hazard = auto-inoculation, ingestion, mucous membrane exposure.	BSL-1 practice plus limited access, biohazard warning signs, "SHARPS" precautions, and biosafety manual defining any needed waste decontamination or medical surveillance policies.	Primary barriers = Class I or II BSC or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials, PPE (laboratory coats; gloves, and face protection) as needed.	BSI-1, autoclave available
3	Communicated via aerosol transmissions, and producing diseases with serious or lethal consequences.	BSI-2 practices plus controlled access, decontamination of all waste, decontamination of lab clothing before laundering, and baseline serum.	Primary barriers = Class I, II BSC other physical containment devices used for all manipulations of agents; PPE (protective lab clothing, gloves, and respiratory protection) as needed.	BSL-2, physical separation from access corridors; self-closing, double-door access exhausted air not recirculated and negative airflow into laboratory.
4	Dangerous/exotic bioagents which pose high risk of life-threatening disease, aerosol-transmitted laboratory infections, or related agents with unknown risk of transmission.	BSL-3 practices plus clothing change before entering; shower on exit, and all material decontaminated on exit from facility.	Primary barrier all procedures conducted in Class III BSC or Class I or II BSC in combination with full-body, air-supplied, positive pressure personnel suit.	BSL-3 plus separate building or isolated zone, dedicated supply/exhaust, vacuum and decontamination systems, and other requirements outlined in the text.

a. Requirements copied verbatim from LIR 300-00-02.0, "Documentation of Safe Work Practices."
b. Source: Office of Health and Safety, Centers for Disease Control and Prevention, Atlanta, Georgia.

ATTACHMENT E

SUMMARY OF BIOSAFETY LEVELS FOR ACTIVITIES IN WHICH EXPERIMENTALLY OR NATURALLY INFECTED VERTEBRATE ANIMALS ARE USED OR HANDLED[a, b]

Biosafety Level (BSL)	Agents	Practices	Safety Equipment (Primary Barrier)	Facilities (Secondary Barrier)
1	Not known to cause disease in healthy adults.	Standard animal care and management practices, including appropriate medical surveillance programs.	As required for normal care of each species.	Standard animal facility; non-recirculation of exhaust air, direction airflow recommended.
2	Associated with human disease, hazard = percutaneous exposure, ingestion, mucous membrane exposure.	Animal BSL-1 plus limited access; biohazard warning signs; "SHARPS" precautions; Biosafety manual; decontamination of all infectious wastes and of animal cages washing.	Animal BSL-1 equipment plus containment equipment appropriate for animal species; PPE: laboratory coats, gloves, face and respiratory protection as needed.	Animal BSI-1 plus autoclave; handwashing sink in the animal room.
3	Indigenous or exotic agents with potential for aerosol transmission; disease may have serious health effects.	Animal BSI-2 practices plus controlled access; decontamination of lab clothing before laundering; Cages decontaminated before bedding removed; and disinfectant footbath as needed.	Animal BSL-2 equipment plus containment equipment for housing animals and cage dumping activities; I or II BSCs available for manipulative procedures (inoculation, necropsy) that may create infectious aerosols. PPE: appropriate respiratory protection.	Animal BSL2 plus physical separation from access corridors; self-closing, double-door access; sealed penetrations, sealed windows, autoclave in facility.
4	Dangerous/exotic agents which pose high risk of life threatening disease; aerosol transmission, or	Animal BSL-3 practices plus entrance through change room where personal clothing is	Animal BSL-3 equipment plus maximum containment equipment (i.e., Class III BSC or	Animal BSL-3 plus separate building or isolated zone; dedicated supply/exhaust, vacuum and

	related agents with unknown risk of transmission.	removed and laboratory clothing is put on; shower on exiting; all wastes are decontaminated before removal from the facility.	partial containment equipment in combination with fullbody, air-supplied positive-pressure personnel suit used for all procedures and activities.	decontamination systems and other requirements outlined in the text of 7.3.1.1

a. Requirements copied verbatim from LIR 300-00-02.0, “Documentation of Safe Work Practices.”
b. Source: Office of Health and Safety, Centers for Disease Control and Prevention, Atlanta, Georgia.

ATTACHMENT F

Guidance

RECOMMENDED MAJOR IMPLEMENTATION CRITERIA FOR SELF-ASSESSMENT

(Non-Mandatory)

LIR Title	LIR Number
Biological Safety (Biosafety)	LIR 402-530-00.1

The major implementation criteria listed below are provided to assist Laboratory organizations in assessing their implementation of this LIR on an objective basis. The LIR also states requirements in other areas, such as scope and precautions and responsibilities, which, when applied, complement the major requirements below and support their successful implementation.

- The requirements contained in this LIR have been communicated to the individual(s) responsible for performing the work.
- Operations involving bioagents/biohazards, including collaboration and work for others, are conducted only after IBC review. Proposals are presented to the IBC at the time the proposal is submitted for consideration of funding or at the time of funding renewal.
- Operations involving bioagents/biohazards is conducted only by qualified, trained personnel.
- Employees conduct operations involving bioagents/biohazards using biosafety techniques and adhering to universally accepted guidelines.
- Work involving bloodborne pathogens is covered under the Laboratory Exposure Control Plan Attachment B or a specific exposure control plan.